REMARKS/ARGUMENTS

Claims 1 – 16 are pending in the application.

This amendment corrects the non-compliance issues noted in the Advisory Action, provides appropriate identifiers for all currently amended and new claims, and replaces in its entirely the amendment filed on August 24, 2004.

The Examiner is thanked for the courtesy of a telephone interview conducted on July 15 2004, as well as for his July 23 and 30 comments with regard to proposed claim changes, including the indication that the proposed amendment to claim 14 appears to put that claim into condition for allowance. In conformity therewith, such amended claim 14 is being formally submitted along with this amendment.

New claim 16 has been added pursuant to further telephone discussions with the Examiner.

Applicants respectfully request the withdrawal of the finality of the present Office Action. In particular, since the previous amendment, dated 23 April 2004, contained no amendments to the independent claims, and only minor amendments to two dependent claims for clarification purposes to address informality objections, then pursuant to the beginning of the second paragraph of MPEP section 706.07(a), since the Examiner has introduced a new ground of rejection, the present action should not be made final.

The Examiner is also thanked for the indication that claims 8 – 10 would be allowable. However, in view of the following comments, as well as the amendments made to the claims, it is respectfully submitted that all of claims 1 – 15 should now be

allowable.

Applicants' claim 1 requires, among other features, that their combination probe is "non-implanted". It should be noted that not only is Applicants' device "non-implanted", it is also not capable of being implanted; therefore, if desired by the Examiner, claim 1 could be amended to read "non-implantable" instead of "non-implanted".

The Examiner has rejected claims 1 – 7 and 11 – 15 under 35 USC 102(e) over Guice, stating that the probe of Guice is "non-implanted". However, Applicants respectfully submit that this characterization of the Guice probe is not warranted. Applicants will now demonstrate that in fact the Guice probe must be implanted. This is further supported by the fact that Guice himself throughout his patent specification characterizes his probe element as an implant, which fact should be given considerable weight. In this respect, the Examiner's attention is respectfully directed to paragraph [0034] of Guice where in discussing the prior art used to monitor the health of animals (the Guice system itself is, of course, limited to animals), Guice emphasizes that US Patent 6,113,539 teaches against the use of implants, with Guice in contrast now making such implants possible. For example, in paragraph [0042] Guice teaches that with regard to all of his embodiments the wireless telesensors are telesensor implants 50, 51 that are installed with special implant installation tools 56 (see also Fig. 3).

With regard to the description of the Guice device as being "removable" (although the Examiner indicated such a description as recited in paragraph [0010],

Applicants have been unable to find such a description), it is respectfully submitted that the mere characterization of a device as "removable" does not mean that it is not an implant. In particular, Guice explicitly states that his telesensors are designed to be implanted within the tissue, organs or internal canal of an animal. And, in paragraphs [0157] and [0161] Guice teaches that only telesensors which are implanted can minimize implant drift, toxicity, and contamination. Guice's patent includes 217 paragraphs and 28 Figure drawings. In 50 of these 217 paragraphs, and in 12 of the 28 Figure drawings, Guice uses 352 citations to emphasize that his telesensors are implants by using words such as, "implant", "installed", "installation", "injected, anchored or screwed into the animal's tissue", "surgically implanted", "installed subdermally or percutaneous"(see below for a specific listing of these paragraphs and Figure references.) Further, Guice cites the word "insert" 8 times but it is always used in the context of "the implant is inserted into the ear canal or muscle and cartilage tissue etc." This occurs once in paragraphs [0093], [0166], [0187], and [0201] and twice in paragraphs [179] and [0186].

While the devices of both Guice and the instant application are health related, what may be considered safe and suitable for use in veterinary science is not always applicable to human science. In humans, implants are considered to be medically invasive devices which are subject to safety and health standards governing their suitability for use and are regulated by Federal and State Agencies. Regarding the health, safety and suitability issues, Guice goes to great lengths to teach that his telesensors 50, 51 are in fact "implanted" or firmly installed within an animal's tissue

by an installation attendant 55 using a variety of special installation tools 56 and implant configurations for animals to ensure reliable monitoring with his AAHMS (Automated Animal Health Monitoring System) and to minimize implant drift and associated safety concerns such as toxicity and contamination of the food chain which is subject to governmental regulation.

Therefore, the fundamental difference between "implant" or "non-implant" boils down to two questions: what is Guice's reasoning for teaching that his telesensor is an "implant" versus a "non-implant" and, regarding the use of "implant" as a term of art, what criteria can be used to determine if an electro-mechanical device (foreign object) placed in a body cavity of an animal or human is an "implanted" device or a "non-implanted" device?

Therefore, three sources were used to research the word "implant" as a term of art in the health sciences:

1. The first source was the Encarta Dictionary which states, "4. vt SURG to embed something such as a mechanical device in the body".

2. Second, The Food and Drug Administration (FDA) [21 C.F.R. part 860.3(d)] defines an implant as "a device that is placed into a surgically or naturally formed cavity of a human body and is intended to remain implanted continuously for a period of thirty days or more."

3. The assignee, Athena Feminine Technologies, Inc., of the instant application, received the attached FDA Device Approval Letter dated Apr. 30, 2003. This FDA letter begins by specifically stating that Athena's premarket notification was

approved as a "non-implantable" electrical device in accordance with the following: "*Device Name* is Athena Pelvic Muscle Trainer (PMT); *510(k) Number* is K023905; *Regulation Number* is 21CFR Section 876.5320; *Regulation Name* is Nonimplanted electrical continence device; *Regulatory Class* II; *Product Code* is 78 KPI." Further, the FDA publication titled "Medical Devices" includes "Examples of Non-significant Risk Devices" and, devices such as Athena's with the Product Code 78 KPI are specifically identified as "non-significant risk" devices (NSR). Whereas a "significant risk" (SR) device as defined in 21 CFR 812.3(m) is a device that presents a potential for serious risk to the health, safety, or welfare of a subject and, "1) is an implant; or...(4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject."

Guice, in his ABSTRACT, makes it very clear that his telesensor is an "implant", "The system includes implantable wireless "smart tele-sensors" elements that can be implanted within the animal where they measure, and may transmit, temperature and other parameters (e.g., blood oxygen, accelerations, vibrations, heart rate) related to the health and status of the animal being monitored." Further, Guice also limits the use of his "implants" to livestock and animals. Guice refutes the use of non-implanted devices in paragraph [0034] where, as mentioned previously, he teaches about the limitations found in the prior art of U.S. Patent No. 6,113,539 which uses a removable monitoring sleeve attached to an appendage of an animal. Guice's teaching focuses on the shortcomings of not embedding "implants" into an animal's tissue when he says, "This patent teaches against the use of implants due

to alleged risk of infection. However, we believe that it well (sic) be difficult to install and maintain the removal sleeves taught by this patent...Additionally, the temperatures and other physiological parameters monitored by sensors mounted external to the animal are not likely to be as reliable as the parameters measured by the sensors installed within the animal's tissue are (sic) within cavities in the animal..."

Guice in paragraph [0006] under BACKGROUND OF THE INVENTION first explains his reasoning for using telesensor "implants" as versus "non-implanted" devices. Here, Guice teaches that,"...instrumentation systems are needed within animal production environments to enable more efficient and effective monitoring and control of the animal production process while minimizing the costs of labor and other costs of production."

In paragraph [0010], Guice goes on to teach about the importance of a long term monitoring of animals as follows,"...steers 10 are typically approximately nine months to one year old when they are shipped to feedlot operations, and they may remain in the feedlot environment anywhere from 90 days up to one year, with the most being in the feedlot for approximately 120 to 150 days." Guice's teaching leaves no question that his choice of the word "implant" is a technical term of art which means that installation is required and furthermore is synonymous with the requirement to monitor animals continuously over extended periods of time. Applicants respectfully traverse the Examiner's vague "in the same sense" inference that Guice's "implant" can be redefined as "non-implantable" and "portable" just

because electrical devices use common electrical components and can be put into similar body orifices of different species.

In paragraph [0157], Guice is explicit in teaching about the suitability of the use of "implanted" devices (versus "non-implanted" devices) regarding safety, reliability and health concerns. Guice teaches, "Although an implant may be injected into a portion of an animal which is not used for human food, past experience with electronic implants used for animal identification and other purposes has shown that, for at least some implants designs and implant locations, the implants can drift from the original implant location to other portions of the animal's body. In addition to the likelihood that parameter measurements made by a telesensor implant may be misleading if the implant migrates from its original implanted location, there is another possibility that, although an implant is installed in a portion of an animal not processed for human food, the implant will end up in a location which may be processed into a food product for human or animals." This clearly conveys the fact that such animal "implants" are installed for the long haul, and even if they could be removed, are intended to be permanent implants.

In paragraphs [0033], [0040], [0157] and [0161], Guice's teaching is explicit about the problems of "implant drift" such as cost, practicality, safety, toxicity or contamination if an "implant" is not retrieved before or during the slaughtering process which is stringently regulated by federal and state agencies (e.g., USDA, FDA, EPA and Depts. Of Health) In paragraphs [0035], [0156], Guice also teaches about the practical and cost effective ways to recover the implants, or the alternative

of using certain non-hazardous materials, special coatings or implant locations where recovery or removal of telesensor implants may not be necessary.

In paragraphs [0157] and [0161], Guice teaches that as "implants" (versus "non-implant") are "installed" not only to avoid "implant drift" but also to avoid the consequences of toxicity, contamination and safety which are regulated by government. Throughout his patent filing, Guice consistently uses "implant" and "install" as terms of art. Guice does not in any sense imply or teach that his telesensor are "non-implanted" as per the Examiner's "in the same sense" interpretation. Rather, Guice goes to great lengths to teach that his telesensors are, in fact, "implanted" to avoid "implant drift". Calling Guice's telesensor a "non-implant" is not consistent with Guice's teachings nor is it supported by Figs. 18 and 19 and paragraph [0179] cited by the Examiner, nor is it consistent with Guice's rebuke in paragraph [0034] about the limitations of Patent 6,113,539 (see also page 6 of this amendment).

Regarding portability, Guice teaches in Figs 17, 18 and 19 and paragraph [0179] that the configuration and material of an"implant" can be altered, "...telesensor implants can be inserted into the ear canal or, with appropriate modification, another cavity (e.g., rectum, vagina, nasal) of the animal to be monitored. For such applications and embodiments, the telesensor implant may contain a curved member 293 of plastic or other materials...made of plastic having a spring like action so the curved member can be compressed into a smaller diameter to support installation into the ear canal or other cavity, similar to the action of a snap

ring....the curved member 293 may be made of resilient compressible material such as a foam rubber sponge which can be compressed to support installation, then expand into place to support retention within the ear canal or other cavity.....the outer surface of the implant may be coated with an adhesive to aid retention of the implant..." This teaching is contrary to the idea of "portability."

Despite the appropriate modifications in the shape and material, Guice goes on to teach that the "implant" still requires "installation" by the installation attendant, special installation tools and/or adhesive to aid in retention of the implant within the animal, and precaution about long term compatibility of the implant and tissue damage. The fact that "installation", "special tools" and "adhesives" are required in the installation procedure certainly does not teach or support the Examiner's contention that the telesensor is "non-implanted" and "portable".

Rather, in paragraph [0179], Guice teaches, "Such implants may contain other features which aid in the installation or retraction of the telesensor implant. For example, loops 297 may be added...as illustrated in Fig 16 to permit installation or removal of the implant using a tool similar to a snap ring pliers, suitably modified to reduce the risk of puncturing the eardrum or causing other damage to the animal being monitored. Fig 18 illustrates the addition of tabs 299...Fig 19 illustrates the incorporation of a wire member 301 to provide another means via which the telesensor implant could be grasped by a pliers or a tool containing a hook to support removal of the implant ...The wire could be shaped so it could be inserted in a tube...During installation a pushrod within said tube...Special coating may be added

to the implant in some embodiments to promote long term compatibility with tissues in the ear canal or other cavity without causing necrosis or damage or irritation to such tissues."

The issue of "portability" is not supported by Guice's modifications of loops, tabs, wire members or hooks. These modifications still requires pliers to grasp them, and the use of a tube and pushrod. These certainly add to the invasiveness of the implant and its installation procedure. Guice's use of special coating to promote long term compatibility without causing necrosis, damage or irritation to the tissue certainly teaches that the "implant" is intended to be long term and could result in physiological damage to the tissue where the implant is affixed or embedded.

One of ordinary skill in the art would not rely on the Examiner's "same sense" interpretation to conclude that Guice's vaginally inserted telesensors implants 50, 51, 280, 292 for animals could be suitable for use in other species and thus anticipate Athena's "non-implanted" inserted vaginal probe 21 just because both use common electrical components and can be used in the vagina. It is respectfully submitted that the Examiner's "in the same sense" interpretation directly conflicts with Guice's teachings about the "suitability of use" of "implants" versus "non-implanted" telesensors. Further, Guice reiterates the use of the words "install" or "installation" of "implants" throughout his teachings. For example, in Fig. 3 Guice identifies the person using the installation tools 56 as the installation attendant 55.

The Guice reference consists of 28 figures and 217 paragraphs of text. At least 12 of the 28 figures depict telesensor implants, implant tools, different

configurations of implants, implant needles, injection guns and cutting blades or other modifications to stimulate tissue growth to anchor the telesensor implants to specific locations to prevent implant drift. These depictions can be found in Figs 3, 16, 17, 18, 19, 20, 21, 22, 24, 25, 27, and 28.

Guice's most explicit examples depicting telesensor "implants" can be found in Fig. 3, which identifies wireless telesensor implants 50, 51 and, packaged implant (special) packaging 60 that can be installed in the bodies, tissue, cartilage or cavities of animals with implant installation tools 56. Guice makes no mention or passing reference in this Figure or in any other Figure or paragraph of his text that his telesensors are not implanted.

Further, in Figures 20, 21 and 23 Guice identifies specific means and materials that can be used to promote tissue growth through and around the implant in order to anchor the "implanted" telesensor and/or form a biological seal.

As described above, 50 of the 217 paragraphs contain at least one reference to "implants" in the animals to be monitored as being: installed through injection, insertion or forced into body cavities, tissue, bone, cartilage, subdermally, percutaneously with special tools, needles, blades, incisions, tubes, paired blades, pliers, wires, hooks, tabs, rods, pushrods, adhesives, supports or using other elements of implant packaging such as polyurethane foam, collagen sponge, surgical mesh to promote tissue ingrowth or attachment of tissue which helps anchor or affix the implant into the desired location within the body to prevent implant drift. These references can be found in paragraphs [0034], 0038], [0042], [0073], 0076], [0077],

[0085], [0086], [0087], [0089], [0091], [0093], [0095], [0097], [0098], [0100], [0122], [0123], [0130], [0131], [0132], [0135], [0136], [0137], [0149], [0150], [0155], [0156], [0157], [0159], [0160], [0163], [0166], [0168], [0170], [0171], [0173], [0174], [0179], [0181], [0185], [0186], [0187], [0188], [0189], [0190], [0192], [0199], [0200], [0201].

Conversely, in humans the use of a special tool to install or insert an "implant" or foreign object into a body cavity is considered to be an invasive surgical procedure and is strictly regulated as an implant by the FDA. All of the paragraphs cited reinforce Guice's teachings about the use of the language telesensor "implants" as a term of art for embedding or affixing into body tissue for a long term and/or causing physiologic change such as anchoring, tissue growth or in-growth to prevent "implant drift".

More examples of Guice's teachings about "implants" are found in the following paragraphs:

In paragraph [0086], Guice teaches, "As indicated in Fig. 3, depending on specific needs of different applications environments,...installation depths within tissue...may be designed, in the same or different embodiments..."

In paragraph [0093], Guice teaches, "During in-processing...the installation attendant 55 uses one or more implant tools 56 to insert one or more telesensor implants 50,51 into the appropriate location(s) on the animal 53 (e.g., ear canal, or muscle and cartilage tissue just behind the ear attachment points)."

In paragraph [0100], Guice teaches, "The implants 50, 51 may be installed 158 internally within tissue, within an ear canal or other open cavity, within closed

cavities such as the vagina or rectum..." Guice repeats this in paragraph [0122].

In paragraph [0135], Guice teaches, "The wireless telesensor implants of the instant invention are key components in most embodiments of the instant invention....The telesensor implant 280 also includes supporting 294 and sealing materials 290 and special coatings 296 and other components needed to help provide the physical interface with the body of the animal, and to support installation or removal or recovery or reuse of the telesensor implant.

In paragraph [0155], Guice teaches, "Figs. 12, 17 through 22 illustrate examples of implant configurations which may be injected or otherwise installed entirely within the animal (i.e., under their skin or within tissue or bone) placed within the ear canal or other cavity of the animal..."

In paragraph [0156], Guice teaches, "...it is desirable in implanting the AAHMS system, particularly in an animal production environment, to consider (1) the cost of recovering the implant before or during slaughter and processing of an animal, (2) the risk for product contamination if the implant is not recovered..."

In paragraph [0157], Guice teaches, "Although an implant may be injected into a portion of an animal which is not used for human food, past experience with electronic implants used for animal identification and other purposes has shown that, for at least some implant designs and implant locations, the implant can drift from the original implant location to other portions of the animals body. In addition to the likelihood that parameter measurements made by a telesensor may be misleading, if the implant migrates from its original implanted location, there is another possibility

that, although an implant is installed in a portion of an animal not processed for human food, the implant will end up in a location which may be processed into a food product for humans or animals."

As to Guice's references to PDA's in paragraphs [0038], [0086] and [0099], he teaches that they are used, "... to transfer data to PDA's carried by animal attendants...", "...to provide alert information to appropriate personnel directly or indirectly responsible for responding to alert warnings generated by the system..." or, "... to contain the database needed for correlation for all animals on a large commercial feedlot." With regard to PDA's, Guice in no way teaches that they are used as controllers; rather they are merely data collection, data alert warnings or database devices.

All of Guice's teachings are explicit about his telesensors being "implants" Guice's teachings about "implants" may be clarified by examining the anatomical and physiological differences between human and animals. Guice uses a cow in his examples. There are certain structural and functional differences which are not commonly known particularly with regard to the urogenital tract of cow which would explain Guice's need to implant a telesensor in a cow's vagina.

The attached drawing illustrates the significant difference between the exit point for emptying the bladder of a cow and a woman. In a cow, the urine is routed from the bladder through the urethra which empties into the vagina before it then exits the cow's body through its vaginal/clitoral orifice. In a woman, urine is routed from the bladder through the urethra which exits directly through the urethral orifice.

Therefore, in a cow the telesensor must be implanted into the tissue or it will be swept away as the urine flows from the urethra into the vagina and empties through the vaginal/clitorial orifice. Thus, it would not be physically possible to accomplish long term monitoring as described by Guice in paragraph [0010] nor to prevent implant drift as described in paragraphs [0033], [0040], [0157] and [0161] with non-implanted telesensors.

Guice emphatically teaches that only implanted telesensors allow reliable, economical and continuous monitoring of animals over extended time periods while minimizing implant drift and government regulated safety concerns about toxicity and contamination.

In view of the foregoing discussion, Applicants respectfully request reconsideration of the allowability of all of pending claims 1 – 15. In addition, should the Examiner have any further comments or suggestions, the undersigned respectfully requests a telephone interview in order to resolve any outstanding issues and to finally place the application into condition for allowance.

Respectfully Submitted,

Robert – Becker

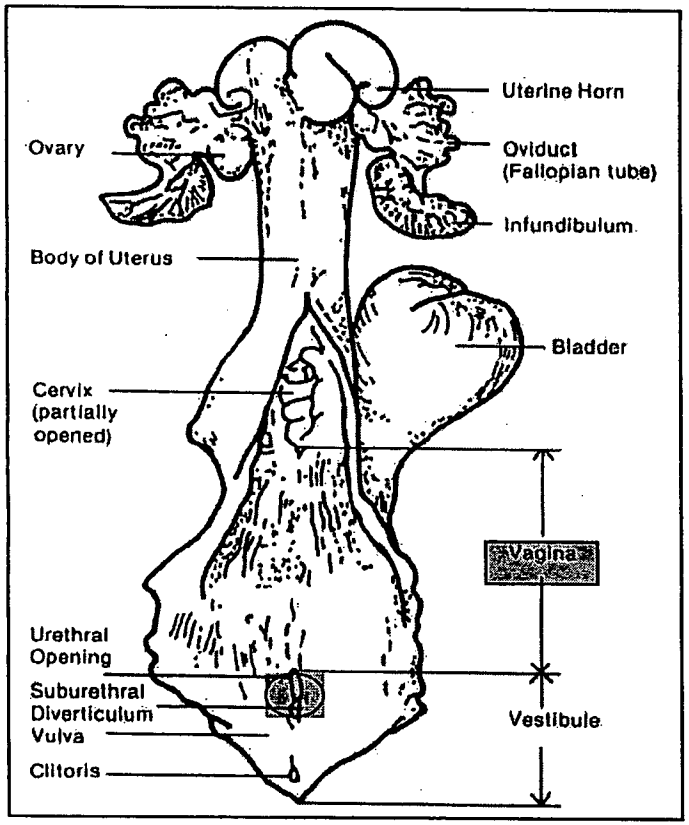
Robert W. Becker, Reg. No. 26,255
for applicants

ROBERT W. BECKER & ASSOCIATES
707 Highway 66 East, Suite B
Tijeras, NM 87059

Telephone: (505) 286-3511
Facsimile: (505) 286-3524

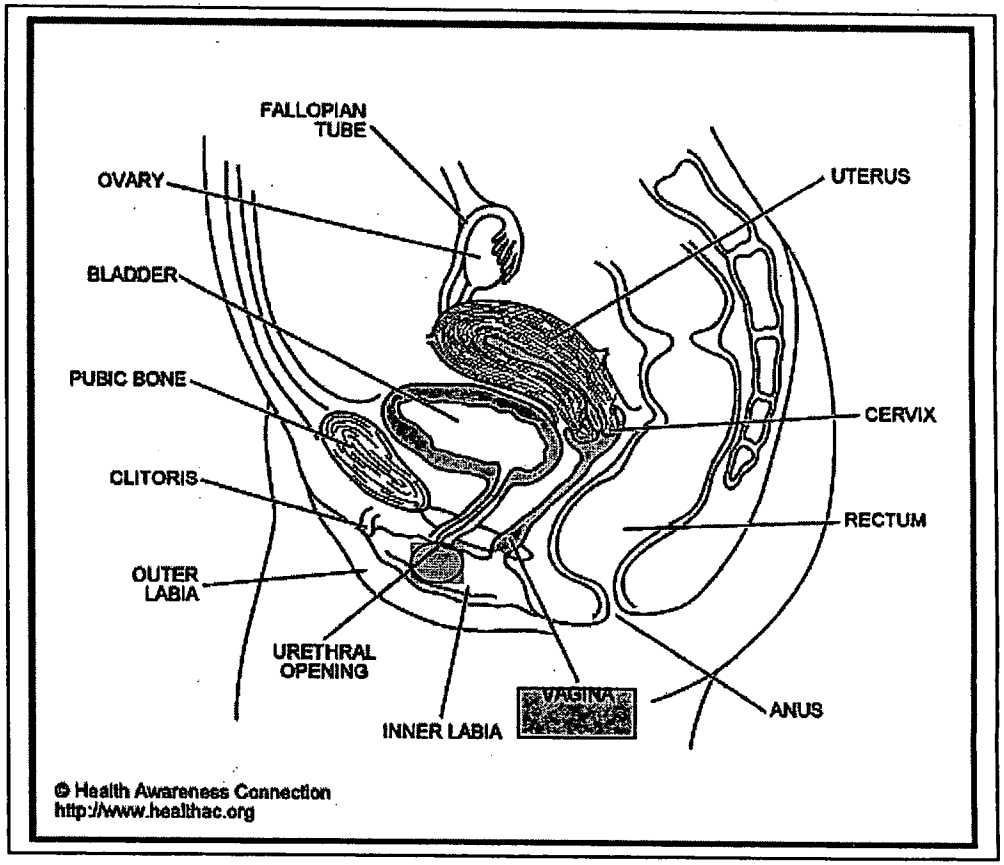
RWB:mac / Attachments

Female Cow



Anatomy of the Cow's Reproductive Tract
Dr. R. W. Prange and Dr. R. T Duby
University of Massachusetts

Female Human



Reference: Health Awareness Connection
www.healthac.org

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2003

Ms. Barbara Sarkis
Chief Information Officer
Athena Feminine Technologies, Inc.
179 Moraga Way
ORINDA CA 94563

Re: K023905
Trade/Device Name: Athena Pelvic Muscle Trainer (PMT)
Regulation Number: 21 CFR §876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: 78 KPI
Dated: March 3, 2003
Received: March 4, 2003

Dear Ms. Sarkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER: K023905

DEVICE NAME: ***Athena Pelvic Muscle Trainer***

INDICATIONS FOR USE:

The **Athena Pelvic Muscle Trainer** is intended to provide electrical stimulation and neuromuscular reeducation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional format 1-2-96)

David A. Lyerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023905